

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

MARJORIE HELEN LEWIS AND
HUSBAND, RONALD LEWIS,

Plaintiffs,

v.

NEW ENGLAND COMPOUNDING
PHARMACY, INC., D/B/A NEW ENGLAND
COMPOUNDING CENTER, AMERIDOSE,
LLC, MEDICAL SALES MANAGEMENT,
INC., BARRY J. CADDEN, GREGORY A.
CONIGLIARO, DOUGLAS A.
CONIGLIARO, LISA CONIGLIARO
CADDEN, CARLA R. CONIGLIARO AND
GLEN A. CHIN,

Defendants.

) CIVIL ACTION NO. 2:12cv00115

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) JUDGE: KEVIN H. SHARP

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) **AMENDED ANSWER OF DEFENDANT
AMERIDOSE, LLC TO PLAINTIFFS'
COMPLAINT**

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Pursuant to Fed. R. Civ. P. 15(a)(1)(A), Defendant Ameridose, LLC, by and through its undersigned counsel, hereby files its Amended Answer to Plaintiffs' Complaint for Damages as follows:

1. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 1.

2. The allegations in Paragraph 2 are not directed to this Defendant so no response is necessary. To the extent one is deemed required, Defendant denies the allegations in Paragraph 2 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

3. Defendant denies that it is a corporation, but states that it is a Massachusetts domestic Limited Liability Company with a principal place of business located at 205 Flanders

Road, Westborough, Massachusetts 01581. Defendant admits that Gregory A. Conigliaro is its agent for service of process.

4. The allegations in Paragraph 4 are not directed to this Defendant so no response is necessary. To the extent one is deemed required, Defendant denies the allegations in Paragraph 4 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

5. Defendant admits that Barry J. Cadden is part owner of Defendant Ameridose. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 5 as to the other Defendants.

6. Defendant admits that Gregory A. Conigliaro is part owner of Defendant Ameridose. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 6 as to the other Defendants.

7. The allegations in Paragraph 7 are not directed to this Defendant so no response is necessary. To the extent one is deemed required, Defendant denies the allegations in Paragraph 7 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

8. Defendant admits that Lisa Conigliaro Cadden is part owner of Defendant Ameridose. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 8 as to the other Defendants.

9. Defendant admits that Carla R. Conigliaro is part owner of Defendant Ameridose. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 9 as to the other Defendants.

10. The allegations in Paragraph 10 are not directed to this Defendant so no response is necessary. To the extent one is deemed required, Defendant denies the allegations in Paragraph 10 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

11. Defendant denies that it designed, manufactured, distributed, sold, marketed, and/or introduced into interstate commerce methylprednisolone acetate (MPA). Defendant is not required to respond to the allegations in Paragraph 11 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 11 as to the other Defendants.

12. Defendant denies that it designed, manufactured, fabricated, compounded, produced, processed, and/or assembled MPA. Defendant is not required to respond to the allegations in Paragraph 12 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 12 as to the other Defendants.

FACTS

13. Defendant denies that it designed, manufactured, fabricated, compounded, produced, processed, assembled, and sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 13 pertaining to Plaintiff's medical condition and treatment.

14. Defendant denies the allegations against it in Paragraph 14. Defendant is not required to respond to the allegations in Paragraph 14 that set forth legal conclusions. However,

to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 14 as to the other Defendants.

15. The allegations in Paragraph 15 are not directed to this Defendant so no response is necessary. To the extent one is deemed required, Defendant denies the allegations in Paragraph 15 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

16. Defendant denies the allegations against it in Paragraph 16. Defendant is not required to respond to the allegations in Paragraph 16 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 16 as to the other Defendants.

17. Defendant denies the allegations against it in Paragraph 17. Defendant is not required to respond to the allegations in Paragraph 17 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 17 as to the other Defendants.

18. Defendant denies the allegations against it in Paragraph 18. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 18 as to the other Defendants and Plaintiff's treatment.

19. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 19.

20. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 20.

21. Defendant is not required to respond to the allegations in Paragraph 21 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 21 as to the other Defendants and Plaintiff's injuries.

WRONGS OF THE DEFENDANTS

22. Defendant is not required to respond to the allegations in Paragraph 22 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 22 as to the other Defendants. Defendant further denies that Douglas A. Conigliaro and Glen A. Chin were owners of Ameridose.

23. Defendant denies that it designed, manufactured, and marketed MPA. Defendant admits that Barry J. Cadden, Gregory A. Conigliaro, Lisa Conigliaro Cadden, and Carla R. Conigliaro are part owners of Ameridose. Defendant is not required to respond to the allegations in Paragraph 23 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 23 as to the other Defendants.

24. Defendant denies that it designed, fabricated, produced, compounded, processed, and/or assembled MPA. Defendant is not required to respond to the allegations in Paragraph 24 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 24 as to the other Defendants.

25. Defendant denies the allegations against it in Paragraph 25 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

26. Defendant is not required to respond to the allegations in Paragraph 26 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 26 as to the other Defendants.

27. Defendant is not required to respond to the allegations in Paragraph 27 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 27 as to the other Defendants.

28. Defendant is not required to respond to the allegations in Paragraph 28 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28 as to the other Defendants.

- a. Defendant denies the allegations against it in Paragraph 28(a) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- b. Defendant denies the allegations against it in Paragraph 28(b) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- c. Defendant denies the allegations against it in Paragraph 28(c) and lacks knowledge or information sufficient to form a belief about the truth of the

allegations as to the other Defendants.

- d. Defendant denies the allegations against it in Paragraph 28(d) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
 - e. Defendant denies that it distributed MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28(e) as to the other Defendants.
 - f. Defendant denies that it manufactured, compounded, sold or distributed MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28(f) as to the other Defendants.
 - g. Defendant denies that it manufactured, compounded, sold or distributed MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28(g) as to the other Defendants.
 - h. Defendant denies that it manufactured, compounded, sold or distributed MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28(h) as to the other Defendants.
 - i. Defendant denies that it manufactured, compounded, sold or distributed MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28(i) as to the other Defendants.
 - j. Defendant denies the allegations against it in Paragraph 28(j) and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
29. Defendant is not required to respond to the allegations in Paragraph 29 that set

forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 29 as to the other Defendants.

INJURIES AND DAMAGES

30. Defendant is not required to respond to the allegations in Paragraph 30 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 30 as to the other Defendants and Plaintiff's injuries.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

DEFENSES AND AFFIRMATIVE DEFENSES

During the course of litigation, a number of defenses and/or affirmative defenses may become available to Defendant. To the extent any of the following are available and may apply, notice is hereby given of the following:

1. The Complaint fails to state a claim or cause of action cognizable in law or equity against Defendant Ameridose.
2. The Complaint fails to allege a cognizable claim for breach of any applicable standard for the practice of pharmacy as to Defendant Ameridose.
3. Plaintiffs lack standing to sue Defendant Ameridose.
4. Defendant did not make the product in question and has no liability here since it is a separate entity not responsible for the acts of the other Defendants.

5. The allegations of the Complaint do not adequately set forth the elements required to overcome the presumption of corporate separateness under applicable state law.

6. The Complaint fails to sufficiently identify a preparation compounded or manufactured by this Defendant.

7. The Defendant further states that if the Plaintiffs underwent the medical procedure, they did so after having been fully, fairly, and reasonably informed and made aware of risks and uncertainties involved, and that after having been so informed consistent with the informed consent doctrine of Tennessee, they exercised their informed consent to the performance of the procedure.

8. The alleged injuries or damages may have been proximately caused by one or more unforeseeable, independent intervening or superseding events beyond the control of and unrelated to the conduct of Defendant, including Plaintiff's comparative fault, pre-existing medical condition, and/or idiosyncratic reaction.

9. Adequate warnings and information were available to the medical profession, including any prescribing or administering healthcare provider.

10. Defendant relies upon all applicable defenses afforded it under the Tennessee Product Liability Act of 1978, Tenn. Code Ann. § 29-28-101, *et seq.*

11. To the extent that Plaintiffs' claims are based on violations of the Federal Food Drug & Cosmetic Act, such claims must fail since there is no private right of action regarding these alleged violations.

12. Defendant denies that any injuries or damages claimed by Plaintiffs were the direct and proximate result of any negligence or other conduct on its part. Defendant further avers that any recovery to which Plaintiffs may be entitled is barred or reduced by the negligence

or acts of third parties or other responsible entities under the doctrine of comparative fault and that Defendant is responsible for only that portion of fault properly allocated to Defendant, which it denies. Although liability is denied, and without conceding or alleging that any co-defendant in this action is liable to Plaintiffs under any theory, pleading in the alternative only and incorporating by reference the allegations in the Complaint as to the co-defendants, Defendant gives notice of its possible intent to rely on the doctrine of comparative fault based on the potential fault of Plaintiffs, co-defendants, and/or other non-parties to reduce and/or bar Plaintiffs' recovery against Defendant at trial.

13. Plaintiffs are not entitled to recover exemplary or punitive damages in this case because such damages would result in violations of the United States Constitution, the Tennessee Constitution, and applicable federal and state law.

WHEREFORE, Defendant demands Judgment of this Court:

- a. dismissing the Complaint against it, with prejudice;
- b. awarding to Defendant the costs, expenses, and fees associated with defending this action; and
- c. granting such other and further relief, both legal and equitable, that the Court deems just and proper.

Dated: December 27, 2012

BUTLER SNOW O'MARA STEVENS & CANNADA, PLLC

/s/ James A. Beakes III

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CERTIFICATE OF SERVICE

I hereby certify that on December 27, 2012, the documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and I served a true and accurate copy of the foregoing document to counsel of record via first class mail as follows:

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/s/ James A. Beakes III

James A. Beakes III